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| APPLICATION NO. | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------|-----------------|----------------------|-------------------------|------------------|
| 09/613,707      | 07/11/2000      | Claudia Lanari       | P02004US0               | 1059             |
| 26271           | 7590 06/18/2002 |                      |                         |                  |
|                 | •               |                      | ЕХАМП                   | NER              |
|                 |                 | DAVIS, NATALIE A     |                         |                  |
| HOUSTON, T      | TX 77010-3095   | •                    | ART UNIT                | PAPER NUMBER     |
|                 |                 |                      | 1642                    | THE EXTROMOLIX   |
|                 |                 |                      | DATE MAILED: 06/18/2002 | 13               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| 1  |   | Application No.          | Applicant(s)                                    |  |  |  |  |
|--|---|--------------------------|---|--|--|--|--|
|  |   | 09/613,707               | LANARI ET AL.                                   |  |  |  |  |
|  | Office Action Summary   | Examiner                 | Art Unit  |  |  |  |  |
|  |   | Natalie A. Davis         | 1642  |  |  |  |  |
| Period fo  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |                          |   |  |  |  |  |
| THE   - External control contr | A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |                          |   |  |  |  |  |
| Status   |   |                          |   |  |  |  |  |
|  | 1) Responsive to communication(s) filed on 18 March 2002.   |                          |   |  |  |  |  |
| · —  | 2a) This action is <b>FINAL</b> . 2b) ☑ This action is non-final.   |                          |   |  |  |  |  |
| ,  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |                          |   |  |  |  |  |
| 4)⊠ Claim(s) <u>5-8,11 and 12</u> is/are pending in the application.   |   |                          |   |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                          |   |  |  |  |  |
| 5)⊠  | 5)⊠ Claim(s) <u>6,7 and 12</u> is/are allowed.  |                          |   |  |  |  |  |
| 6)⊠  | 6)⊠ Claim(s) <u>5 and 11</u> is/are rejected.   |                          |   |  |  |  |  |
| 7)   | 7) Claim(s) is/are objected to.   |                          |   |  |  |  |  |
| 8)   | 8) Claim(s) are subject to restriction and/or election requirement.   |                          |   |  |  |  |  |
| Application Papers   |   |                          |   |  |  |  |  |
| 9)🖾 7  | 9)⊠ The specification is objected to by the Examiner.   |                          |   |  |  |  |  |
| 10)⊠ Т   | 10) $\boxtimes$ The drawing(s) filed on <u>11 July 2000</u> is/are: a) $\square$ accepted or b) $\boxtimes$ objected to by the Examiner.  |                          |   |  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                          |   |  |  |  |  |
| 11) 🔲 T  | 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.  |                          |   |  |  |  |  |
|  | If approved, corrected drawings are required in reply to this Office action.  |                          |   |  |  |  |  |
| 12)□ T   | 12) The oath or declaration is objected to by the Examiner.   |                          |   |  |  |  |  |
| Priority u   | Priority under 35 U.S.C. §§ 119 and 120   |                          |   |  |  |  |  |
| 13) 🔲 🔏  | 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                          |   |  |  |  |  |
| a)[  | a) All b) Some * c) None of:  |                          |   |  |  |  |  |
|  | 1. Certified copies of the priority documents have been received.   |                          |   |  |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No  |                          |   |  |  |  |  |
|  | Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |                          |   |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application of the sertine despites that received.  |   |                          |   |  |  |  |  |
| a)   | a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                          |   |  |  |  |  |
| Attachment(s)  |   |                          |   |  |  |  |  |
| 2) Notice 3) Informa   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Informal Pa | PTO-413) Paper No(s) tent Application (PTO-152) |  |  |  |  |
| U.S. Patent and Trac<br>PTO-326 (Rev.  |   | on Summary               | Part of Paper No. 13                            |  |  |  |  |

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#### **DETAILED ACTION**

Applicant's amendment filed 18 March 2002 (Paper No: 11) is acknowledged. Accordingly, claims 5-8 and 11-12 are pending and under examination.

### Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Oath/Declaration Objection-Withdrawn

1. Objection to the oath/declaration is withdrawn in view of submission of new oath.

## Specification Objection-Maintained

2. Objection to the specification is maintained. Even though applicants have amended the specification to include the place and date of where the cell line has been deposited, the instant application does not provide the appropriate evidence of satisfying the deposit of the plasmid for the enforceable life of the patent. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection.

# Claim Rejections - 35 USC § 102 Withdrawn

3. Rejection of claims 5 and 11 over Dran, et al, (1995) under 35 U.S.C. 102(b) is withdrawn in view of arguments.

# Claim Rejections - 35 USC § 103

4. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dran, et al., (1995).

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Applicants argue that Dran, et al., does not anticipate the invention as claimed under 102 (b) because Dran teaches the use of primary cultures and not cell lines as in the instant application. Primary cultures cease dividing, which is the opposite of cell lines that divide infinitely. However, since Dran, et al. set forth murine mammary adenocarcinoma cell lines with estrogen and progesterone receptors, derived from progestin-independent and progestin-dependent tumors (p. 174, col. 2). Dran, et al, further disclose a method of testing the activity of hormones and anti-hormones on the cell lines by quantifying cell proliferation using 3H-thymidine and/or autoradiography and immunocytochemistry. It would have been obvious to one of ordinary skill in the art to use a cell line instead of a primary culture to study the in vitro effects of hormones on the cell line. One would have been motivated to determine the effects hormones have on this cell line in order to determine how to treat mammary cancer since the cell line was derived from cancer. Likewise it would have been obvious to use a kit as in claim 11 to use in a method to test the activity of hormones and anti-hormones on the cell line. The rejection may be overcome if the claims were to recite the accession number of the cell line.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD. June 8, 2002

ANTHONY C. CAPUTA
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